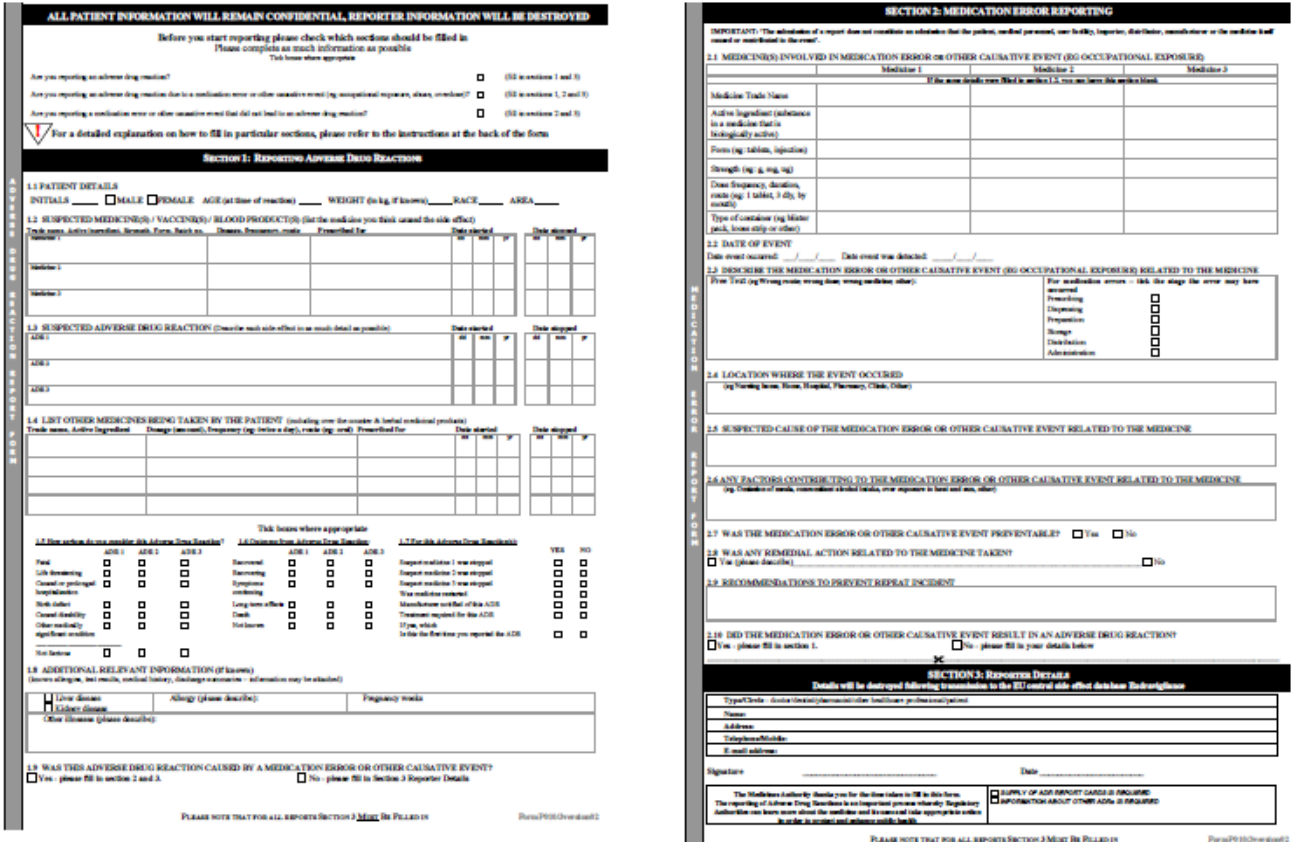

ALL PATIENT INFORMATION WILL REMAIN CONFIDENTIAL, REPORTER INFORMATION WILL BE DESTROYED

Before you start reporting please check which sections should be filled in
Please complete as much information as possible
Tick boxes where appropriate

Are you reporting an adverse drug reaction? ☐ (fill in sections 1 and 3)

Are you reporting an adverse drug reaction due to a medication error or other causative event (eg occupational exposure, abuse, overdose)? ☐ (fill in sections 1, 2 and 3)

Are you reporting a medication error or other causative event that did not lead to an adverse drug reaction? ☐ (fill in sections 2 and 3)

For a detailed explanation on how to fill in particular sections, please refer to the instructions at the back of the form

SECTION 1: REPORTING ADVERSE DRUG REACTION

1.1 PATIENT DETAILS
INITIALS _____ ☐MALE ☐FEMALE AGE (at time of reaction) _____ WEIGHT (in kg, if known) _____ RACE _____ AREA _____

1.2 SUSPECTED MEDICINE(S) / VACCINE(S) / BLOOD PRODUCT(S) (list the medicine you think caused the side effect)

Trade name, Active Ingredient, Strength, Form, Batch no.	Dosage, Frequency, route	Prescribed For	Date started dd mm yy	Date stopped dd mm yy
Medicine 1				
Medicine 2				
Medicine 3				

1.3 SUSPECTED ADVERSE DRUG REACTION (Describe each side effect in as much detail as possible)

	Date started dd mm yy	Date stopped dd mm yy
ADR 1		
ADR 2		
ADR 3		

1.4 LIST OTHER MEDICINES BEING TAKEN BY THE PATIENT (including over the counter & herbal/traditional products)

Trade name, Active Ingredient	Dosage (amount), Frequency (eg. 1mg x 1day), route (eg. oral)	Prescribed For	Date started dd mm yy	Date stopped dd mm yy

Tick boxes where appropriate

1.5 How serious do you consider this Adverse Drug Reaction?

	ADR 1	ADR 2	ADR 3
Fatal	☐	☐	☐
Life threatening	☐	☐	☐
Caused or prolonged hospitalisation	☐	☐	☐
Birth defect	☐	☐	☐
Caused disability	☐	☐	☐
Other medically significant condition	☐	☐	☐
Not Serious	☐	☐	☐

1.6 Outcome from Adverse Drug Reaction

	ADR 1	ADR 2	ADR 3
Recovered	☐	☐	☐
Recovering	☐	☐	☐
Symptoms continuing	☐	☐	☐
Long term effects	☐	☐	☐
Death	☐	☐	☐
Not known	☐	☐	☐

1.7 For the Adverse Drug Reaction(s)

	YES	NO
Suspect medicine 1 was stopped	☐	☐
Suspect medicine 2 was stopped	☐	☐
Suspect medicine 3 was stopped	☐	☐
The medicine restarted	☐	☐
Manufacturer notified of this ADR	☐	☐
Treatment required for this ADR	☐	☐
If yes, which		
Is this the first time you reported the ADR	☐	☐

1.8 ADDITIONAL RELEVANT INFORMATION (If known)
(known allergies, test results, medical history, discharge summaries – information may be attached)

☐ Liver disease ☐ Kidney disease	Allergy (please describe):	Pregnancy weeks
Other illnesses (please describe):		

1.9 WAS THIS ADVERSE DRUG REACTION CAUSED BY A MEDICATION ERROR OR OTHER CAUSATIVE EVENT?
☐ Yes - please fill in section 2 and 3. ☐ No - please fill in Section 3 Reporter Details

PLEASE NOTE THAT FOR ALL REPORTS SECTION 3 MUST BE FILLED IN

FormP010Overview02

SECTION 2: MEDICATION ERROR REPORTING

IMPORTANT: The submission of a report does not constitute an admission that the patient, medical personnel, care facility, importer, distributor, manufacturer or the medicine itself caused or contributed to the event.

2.1 MEDICINE(S) INVOLVED IN MEDICATION ERROR OR OTHER CAUSATIVE EVENT (EG OCCUPATIONAL EXPOSURE)

	Medicine 1	Medicine 2	Medicine 3
	If the same details were filled in section 1.3, you can leave this section blank		
Medicine Trade Name			
Active Ingredient (substance in a medicine that is biologically active)			
Form (eg: tablets, injection)			
Strength (eg: g, mg, ug)			
Dose Frequency, duration, route (eg: 1 tablet, 3 dly, by mouth)			
Type of container (eg blister pack, loose strip or other)			

2.2 DATE OF EVENT
Date event occurred: ___/___/___ Date event was detected: ___/___/___

2.3 DESCRIBE THE MEDICATION ERROR OR OTHER CAUSATIVE EVENT (EG OCCUPATIONAL EXPOSURE) RELATED TO THE MEDICINE

Free Text (eg Wrong route, wrong dose, wrong medicine other):

For medication errors – tick the stage the error may have occurred

Prescribing	☐
Dispensing	☐
Preparation	☐
Storage	☐
Distribution	☐
Administration	☐

2.4 LOCATION WHERE THE EVENT OCCURED
(eg Nursing home, Home, Hospital, Pharmacy, Clinic, Other)

2.5 SUSPECTED CAUSE OF THE MEDICATION ERROR OR OTHER CAUSATIVE EVENT RELATED TO THE MEDICINE

2.6 ANY FACTORS CONTRIBUTING TO THE MEDICATION ERROR OR OTHER CAUSATIVE EVENT RELATED TO THE MEDICINE
(eg. Omission of meds, concomitant alcohol intake, over exposure to heat and sun, other)

2.7 WAS THE MEDICATION ERROR OR OTHER CAUSATIVE EVENT PREVENTABLE? ☐ Yes ☐ No

2.8 WAS ANY REMEDIAL ACTION RELATED TO THE MEDICINE TAKEN?
☐ Yes (please describe) _____ ☐ No

2.9 RECOMMENDATIONS TO PREVENT REPEAT INCIDENT

2.10 DID THE MEDICATION ERROR OR OTHER CAUSATIVE EVENT RESULT IN AN ADVERSE DRUG REACTION?
☐ Yes - please fill in section 1. ☐ No - please fill in your details below

SECTION 3: REPORTER DETAILS
Details will be destroyed following transmission to the EU central side effect database Eudravigilance

Type/Circle: doctor/dentist/pharmacist/other healthcare professional/patient	
Name:	
Address:	
Telephone/Mobile:	
E-mail address:	

Signature _____ Date _____

The Medicines Authority thanks you for the time taken to fill in this form.
The reporting of Adverse Drug Reactions is an important process whereby Regulatory Authorities can learn more about the medicine and it's associated risks appropriate action to be taken to protect and enhance public health.

☐ SUPPLY OF ADR REPORT CARDS IS REQUIRED
☐ INFORMATION ABOUT OTHER ADRs IS REQUIRED

PLEASE NOTE THAT FOR ALL REPORTS SECTION 3 MUST BE FILLED IN

FormP010Overview02

Figure 1 **Final design of the new national adverse drug reaction/medication error reporting form for Malta**